



UNITED STATES PATENT AND TRADEMARK OFFICE

cll

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/081.736	02/20/2002	Justin R. Fallon	BURF-P02-006	2816
28120	7590	06/22/2006	EXAMINER	
FISH & NEAVE IP GROUP ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624			CHERNYSHEV, OLGA N	
			ART UNIT	PAPER NUMBER
			1649	

DATE MAILED: 06/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/081,736

Applicant(s)

FALLON ET AL.

Examiner

Olga N. Chernyshev

Art Unit

1649

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 April 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 13, 16, 32 and 34-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 13, 16, 32 and 34-38 is/are rejected.
- 7) ☒ Claim(s) 39 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

1. Claims 13 and 39 have been amended and claims 15 and 33 have been canceled as requested in the amendment filed on April 07, 2006. Following the amendment, claims 13, 16, 32 and 34-39 are pending in the instant application.

Claims 13, 16, 32 and 34-39 are under examination in the instant office action.

2. The Text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.

4. Applicant's arguments filed on April 07, 2006 have been fully considered but they are not deemed to be persuasive for the reasons set forth below.

Claim Rejections - 35 USC § 102

5. Claims 13, 16 and 32-38, as amended, stand rejected under 35 U.S.C. 102(b) as being anticipated by Ruoslahti et al., US Patent No. 5,654,270 for reasons of record in previous communications of record.

In reply filed on April 07, 2006 Applicant essentially presents the same arguments as fully answered earlier. Briefly, Applicant argues that because publication of Ruoslahti et al. fails to specifically recite potentiation of agrin-induced phosphorylation of MuSK during contact of biglycan with a muscle cell membrane such as in claim 13, then the publication fails to anticipate the claimed subject matter. Applicant urges that differences in concentration of biglycan used by

Art Unit: 1649

Ruoslahti et al. (high levels) and in the instant specification (1.4 nM to potentiate MuSK and above 140 nM to inhibit MuSK, see p. 83 of the instant specification) would prevent one skilled in the art “to develop a method for administering a biglycan therapeutic in an amount effective to potentiate agrin-induced phosphorylation of MuSK” (bottom at page 5 of the Response).

Applicant’s arguments have been fully considered but are not persuasive for the reasons of record fully explained earlier and briefly repeated below.

Because the instant claims are broadly drawn to a method for activating a membrane of a cell, wherein the method step is limited to contacting the cell with biglycan, and because the patent of Ruoslahti et al. expressly describes administration of biglycan to a wound comprising cells expressing MuSK, one would reasonably expect that such contact of biglycan and cell membrane would lead to activation of MuSK, absent evidence to the contrary. As fully explained earlier, the scientific explanation of a previously unappreciated property of a prior art's functioning, does not render the old procedure patentably new to the discoverer, as the results of the same procedure are reasonably expected to be the same. If, according to Applicant, only extremely low doses of biglycan are effective to potentiate agrin-induced phosphorylation of MuSK, this by itself raises issues of scope of enablement under 35 U.S.C. 112, first paragraph. However, at the moment, since the instant claims are not limited to specific “effective amount” of biglycan, publication of Ruoslahti et al. meets all the limitations of the instant invention, as currently claimed and the instant rejection is maintained.

Conclusion

6. Claims 13, 16, 32 and 34-38 are rejected. Claim 39 is objected to for being dependent from rejected claim. Claims 13, 16, 32 and 34-39 would be allowable if rewritten to include the effective concentration of biglycan, which would distinguish the instant claims and the prior art of record, and also would support the enablement of the instant invention for that particular concentration in view of biphasic effect of biglycan.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).


A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Olga N. Chernyshev whose telephone number is (571) 272-0870. The examiner can normally be reached on 8:00 AM to 5:00 PM.

Art Unit: 1649

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached on (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Olga N. Chernyshev, Ph.D.
Primary Examiner
Art Unit 1649

June 19, 2006